Stannane, butyltrichloro-: Human health tier II assessment

21 April 2016

CAS Number: 1118-46-3

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

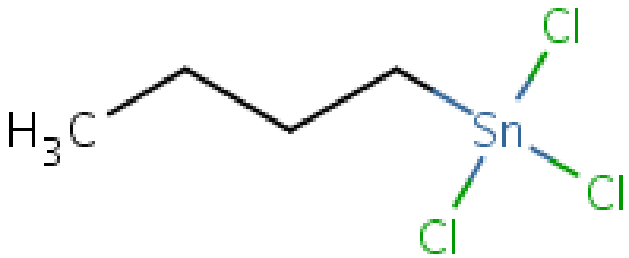
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:www.nicnas.gov.au

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	monobutyltin trichloride mono-n-butyltin trichloride butyltin trichloride MBTC Butylstannium trichloride
Structural Formula	
Molecular Formula	C4H9Cl3Sn
Molecular Weight (g/mol)	282.18
Appearance and Odour (where available)	Yellow liquid
SMILES	C(CCC)[Sn](Cl)(Cl)Cl

Import, Manufacture and Use

Australian

The chemical was reported under previous mandatory and/or voluntary calls for information as being used in the use category of lubricants and additives. The National Pollutant Inventory (NPI) holds data for all sources of organotin compounds emissions in Australia.

International

The following international uses have been identified through; the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; the Organisation for Economic Co-operation and Development Screening information data set International Assessment Report (OECD SIAR); Galleria Chemica; the United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; the OECD High Production Volume chemical program (OECD HPV); the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR); the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); and various international assessments (CDC, 1976, EFSA, 2004; ATSDR 2005; WHO, 2006).

Monobutyltin compounds are used as chemical intermediates, stabilisers for polyvinyl chloride (PVC) and in glass coating applications. Specifically, the chemical has reported use as a chemical intermediate (generally lower purity) and for use in glass coatings applications (generally higher purity). The chemical is reported to be converted to tin oxide during the glass coating process.

Restrictions

Australian

No known restrictions have been identified.

International

Organotin compounds are restricted for biocide and water treatment uses by Annex XVII to the REACH Regulations (European Parliament and Council 2006).

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not listed on the Hazardous Substances Information System (HSIS) (Safe Work Australia).

Exposure Standards

Australian

The chemicals (organic tin compounds) have an exposure standard of 0.1 mg/m^3 time weighted average (TWA) and 0.2 mg/m^3 short-term exposure limit (STEL) with skin notation. This indicates that absorption through the skin could be a significant source of exposure (Safe Work Australia).

International

The following exposure standards are identified for tin organic compounds (as Sn) (Galleria Chemica).

An exposure limit of 0.1 mg/m^3 time weighted average (TWA) and 0.2 mg/m^3 short-term exposure limit (STEL) has been established in different countries such as: Bulgaria; Canada; Chile; Denmark; Egypt; Estonia; France; Greece; Malaysia; Mexico; South Africa; Spain; Sweden; Switzerland; Taiwan; the United States of America and the United Kingdom.

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a threshold limit value (TLV) of 2 mg/m^3 TWA. 'This value is intended to minimize the potential for adverse effects on immune function and the central nervous system. A TLV–STEL of 0.2 mg/m^3 STEL Sn/m^3 is also recommended to minimize acute symptoms such as eye and upper respiratory tract irritation, headaches and nausea.' (ACGIH 2011).

Health Hazard Information

Organotin compounds are characterised by a tin-carbon bond and have the general formula $R_xSnX_{(4-x)}$. The toxicity of organotin compounds depends largely on the organotin moiety (R group) with the anionic ligand (X) mostly influencing physicochemical properties. In general, the systemic toxicity of organotin compounds decreases from the tri- to monoorganotins (ATSDR, 2005; ACGIH, 2011). The chemical is generally manufactured as a mixture with dibutyltin dichloride [DBTC, CAS No. 683-18-1]. The MBTC content in MBTC:DBTC mixtures varies. The chemical, tributyltin chloride (TBTC), may also be an impurity at low levels (OECD, 2006).

Toxicokinetics

Limited data are available on the kinetics and metabolism of organotin compounds.

Organotin compounds can be absorbed following all routes of exposure, although they are reported to have limited gastrointestinal bioavailability (ACGIH, 2011). Five days following a single oral dose of 180 µmol/kg of monobutyltin, urinary excretion of tin (percent of dose) was approximately 0.3 %. This study indicated that the chemical has lower absorption through the digestive tract and low uptake in the liver compared with DBTC (ATSDR, 2005; OECD, 2006).

Similarly to DBTC, the butyl group may be oxidised to form hydroxybutyl derivatives (ATSDR, 2005).

Acute Toxicity

Oral

The chemical has low to moderate acute toxicity based on results from animal studies following oral exposure. Overall hazard classification for acute toxicity is not considered warranted.

The acute toxicity of the chemical was assessed in Wistar rats (five animals/sex/dose), at doses of 500, 1000, 1400, 2000, 2800 or 4000 mg/kg bw. The reported median lethal dose (LD50) was > 2000 mg/kg bw. Observed sublethal signs included apathy and body weakness (cachexia) (OECD, 2006; REACH). The LD50 values in other studies in rats ranged from 357–4000 mg/kg bw with the majority of studies > 2000 mg/kg bw. Other reported sub-lethal signs included nasal and oral discharge, dyspnoea, wet rales, urinary staining, ruffled hair coat, emaciation, hypoactivity and decreased food consumption. Hyperaemia, emphysema and lung lesions, haemorrhagic erosion/high grade bleeding of the mucosal glands in the stomach, swelling and

bloody infiltration of mesenteric lymph nodes, intestinal and pancreatic bleeding, and necrosis in the liver and kidneys were also reported (CDC, 1976; WHO, 2006; OECD, 2006; REACH; RTECS).

In a study in mice (five animals/sex/dose), administration of the chemical was by oral gavage at doses of 0, 200, 400, 800, 1200, 1600, 2400, 3200, 4000 or 6000 mg/kg bw. The LD50 value was reported at 1400 mg/kg bw. Observed sublethal signs included muscular weakness, apathy, ventro-lateral recumbency and laboured respiration (OECD, 2006; REACH). Changes in the liver, kidneys and stomach of mice were consistent with findings in rats. The LD50 values in other studies in mice ranged from 1240 - 4000 mg/kg bw (OECD, 2006; REACH; WHO, 2006)

Reported effects in rats and mice included haemorrhaging in the stomach as well as extensive intestinal bleeding.

Dermal

Limited data are available. In a non-guideline study using albino rabbits (further information not available), the chemical was applied as a 5 % solution in mineral oil for a 24 hour exposure time. The reported LD50 was 630 mg/kg bw. Observed sublethal effects included severe local injury to the skin, and in some animals, necrosis at the application site (TSCATS). Overall, the data are not suficient for hazard classification for acute dermal toxicity. The reported effects are consistent with the corrosive nature of the chemical.

Inhalation

No data are available.

Corrosion / Irritation

Corrosivity

Corrosive chemicals are considered to cause irreversible effects on the eyes and skin; the available eye and skin irritation data for the chemical support this finding. Based on the skin and eye effects, the chemical is recommended for classification (refer **Recommendation** section).

The skin irritation potential of the chemical was assessed in New Zealand White rabbits (three animals/sex/dose). The chemical was applied to the shaved skin on the back of the animals, under occlusive conditions for four hours. The mean erythema and oedema scores were 4 and 2.17, respectively, at 30 minutes after exposure. Severe erythema in all animals was accompanied by severe tissue destruction at the application site including necrosis, eschar formation or lesions (OECD, 2006; REACH). Reversibility of the effects was not determined as the animals were sacrified at 30 minutes after exposure.

The eye irritation potential of the chemical was assessed in New Zealand White rabbits in two studies with a single dose of 0.1 mL instilled in one eye of each animal. The mean scores for cornea (opacity), cornea (area), conjuctivae (redness), conjunctivae (chemosis) were 4.0, 4.0, 0.5 and 1.67, respectively in one study (six animals/dose) (REACH). The mean cornea (opacity), cornea (area), conjuctivae (redness), conjunctivae (chemosis), conjunctivae (discharge) scores were 4.0, 4.0, 0.5, 1.67 and 2.17, respectively, after one hour exposure in another study (six animals/dose) (REACH). Iris scores for both studies were not recorded due to necrosis, and all animals exhibited severe conjunctival and corneal tissue destruction. Reversibility of the effects were not determined as the animals were sacrified for humane reasons after exposure (REACH).

Sensitisation

Skin Sensitisation

No data are available for the chemical. The chemical is considered to be corrosive to skin.

Repeated Dose Toxicity

Oral

Based on the data available, the chemical is not considered to cause serious damage to health through repeated oral exposure.

The repeated dose oral toxicity of the chemical was assessed in a 90-day study in accordance with OECD Test Guideline (TG) 408 in Wistar rats (10 animals/dose). The chemical was administered in the diet at approximately 19, 96 or 521 mg/kg bw/day in males and 20, 101 or 533 in females. The no observed adverse effect level (NOAEL) was reported at 96 and 101 mg/kg bw/day in males and females, respectively, based on treatment-related changes indicating damage to the liver. These effects included haematology, clinical chemistry and liver weight changes at the highest dose.

At the highest dose, a significant increase in triglycerides was reported in both sexes in addition to a significant increase in alkaline phosphatase (ALP), aspartate aminotransaminase (AST), gamma-glutamyl transferase (GGT), albumin/globulin (A/G) ratio, bile acids, phospholipid and potassium levels in males. The total numbers of white blood cells and lymphocytes were also significantly increased in males at the highest dose (OECD, 2006; REACH). There were no corresponding histopathological changes.

Based on absence of histopathological findings in the thymus, the immunotoxic effects observed for dibutyltin compounds (NICNASa; NICNASb) are not expected for the chemical.

Dermal

No data are available.

Inhalation

Based on the data available, the chemical is not considered to cause serious damage to health through repeated exposure by the inhalation route. Observed effects were consistent with the corrosive nature of the chemical and are not considered relevant for classification for this endpoint.

The repeated inhalation toxicity of the chemical was assessed in a study in Sprague Dawley (SD) rats (35 animals/sex/dose) at concentrations of 0, 2,4, 23.8, 71.3 mg/m^3 for six hours/day, five days/week over four weeks' exposure. The reported no observed effect concentration (NOAEC) was considered to be 23.8 mg/m^3 based on clinical signs and mortalities at the highest dose. Observed clinical signs most pronounced in the highest dose group included: nasal discharge; rales; lacrimation; salivation; rough coat; ano-genital staining; discolouration of the fur and abdominal distension in males.

Haematological findings included slightly increased mean haemoglobin, mean erythrocyte count, mean haematocrit in both sexes, most of which were reversible within four weeks. Pulmonary findings were consistent with the corrosivity of the chemical and included lesions, discolouration, alveolar oedema, accumulation of peribronchial lymphoid cells, alveolar macrophage and neutrophillic infiltrates in addition to dose-dependent extravasated alveolar erythrocytes in males. Dermal (hyperkeratosis) and stomach (haemorrhage) effects were attributed to the corrosivity of the chemical (OECD, 2006; REACH).

Genotoxicity

Based on the weight of evidence from the available in vitro and in vivo genotoxicity studies, the chemical is not considered to be genotoxic. The majority of in vitro genotoxicity tests and an in vivo micronucelus test produced a negative result.

The chemical produced a negative result for genotoxicity in the following in vitro tests (OECD, 2006; REACH);

- Bacterial reverse mutation assay in *Salmonella typhimurium* in strains TA 98, TA 100, TA 1535, TA1537, and in *Escherichia coli* WP2 uvrA, with and without metabolic activation at concentrations up to 5000 µg/plate;

- Rec-assay in *Bacillus subtilis* at concentrations up to 10 mg/50 µL;
- Chromosomal aberration test in Chinese hamster ovary (CHO) cells, at concentrations up to 500 µg/ml, with and without metabolic activation; and
- Mammalian cell gene mutation assay in Chinese hamster cells in accordance to OECD TG 476 for concentrations up to 1200 µg/ml, with and without metabolic activation.

The chemical was positive as an SOS response inducer and induced gene mutations in *Salmonella typhimurium* strain TA100 in an SOS chromotest, when tested in the absence of metabolic activation. However, these studies were not in accordance with OECD TGs (OECD, 2006).

The in vivo mutagencity of the chemical was assessed in a micronucleus assay in accordance with OECD TG 474 in ICR mice (five animals/sex/dose). The chemical was administered by oral gavage at doses of 0, 10, 50, and 250 mg/kg bw. No increase in induced chromosomal or other damage leading to micronucleus formation in polychromatic erythrocytes was reported (OECD, 2006; REACH).

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

Based on the data available, there is no evidence of reproductive toxicity. Developmental effects were observed only secondary to maternal toxicity, and were consistent with the corrosivity of the chemical. The developmental toxicity shown by disubstituted alkyltins is not exhibited in the corresponding monosubstituted compound (WHO, 2006).

The reproductive and developmental toxicity of the chemical was assessed in male Wistar rats in a previously described 90-day study (See **Repeat Dose Toxicity- Oral**) and female Wistar rats. Females received the chemical for two weeks from before gestation until postnatal day four (10 animals/sex/dose). No significant treatment-related reproductive effects were observed in the parental generation and no significant changes in developmental parameters were observed in offspring. The NOAEL was determined to be the highest dose at 433-685 mg/kg bw/day in females and 521 mg/kg bw/day in males (OECD, 2006; REACH).

In another study conducted similarly to OECD TG 414; female Wistar rats were administered the chemical by oral gavage at doses of 0, 50, 100, 200 or 400 mg/kg bw/day on gestation day (GD) seven until GD 17. A dose-dependent, but significant, reduction in maternal thymus weight was reported in the absence of further maternal toxicity. No dose-dependent developmental toxicity was evident (OECD, 2006; WHO, 2006).

In a developmental study, pregnant Wistar rats were administered the chemical by oral gavage at 0, 1000, 1500 or 2000 mg/kg bw/day (10, 10, 11, and 6 animals at each dose, respectively) on GD seven and eight. At doses of 1500 and 2000 mg/kg bw/day, maternal mortalities occurred (45 % and 100 %, respectively). Upon necroscopy, mortalities were attributed to haemorrhage of the stomach. Reduced maternal bodyweight was reported at doses of 1000 mg/kg bw/day. There were no significant differences in numbers of litters, resorptions, post-implantation losses or numbers of live foetuses. Foetal body weights were significantly lower at 2000 mg/kg bw/day. Some foetal malformations were observed at doses of 1000 and 1500 mg/kg bw/day (OECD, 2006; WHO; 2006).

In a developmental study, pregnant Wistar rats were administered the chemical by oral gavage at 56, 226, or 903 mg/kg bw/day (16 animals/dose) on GD zero to three, or GD four to seven. Maternal toxicity was reported at the highest dose, including significant decrease in body weight gain and food consumption. Reduced pup weight was also reported at the highest dose. One foetus showed anal atresia and anury in the 226 mg/kg bw/day group (GD zero to three) and the incidence of post-implantation loss was significant in the 56 mg/kg bw/day group (GD four to seven) (OECD, 2006). However, neither of these effects were reported at the higher doses or dose-dependent and thus are not considered toxicologically relevant. (OECD, 2006).

The chemical has been reported not to be an inhibitor of aromatase activity or human 5α-reductase type1 and 5 α-reductase type 2 enzymes (ATSDR, 2005).

Other Health Effects

Neurotoxicity

Organotin compounds have reported neurotoxic effects; however, most data available are for trialkylated tin compounds. In general, the systemic toxicity of organotin compounds decreases from the tri- to mono- alkylorganotins. The results of the neurobehavioural observations and motor activity assessment in the repeated dose oral toxicity study (refer **Repeated dose toxicity:oral** section) did not indicate any neurotoxic potential of the test substance.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation are local effects (corrosivity). Based on the available data, the systemic effects observed with di- and tri- alkyl substituted organotins compounds (immunotoxicity, neurotoxicity, reproductive and developmental toxicity) are not of concern for the chemical.

Public Risk Characterisation

Given the uses identified for the chemical, it is unlikely that the public will be directly exposed to the chemical. Therefore, the chemical is not considered to pose an unreasonable risk to public health.

Although the public could be exposed to the chemical by release from the article at low levels, based on its use as a PVC stabiliser and catalyst for various products, the chemical is considered to have low systemic toxicity.

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation (if aerosols are generated) exposure may occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemical at lower concentrations could also occur while using formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the local health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure are implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine the appropriate controls.

The data available support an amendment to the hazard classification in the HSIS (Safe Work Australia) (refer to **Recommendation** section).

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended amendment to the classification is adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Irritation / Corrosivity	Causes burns (C; R34)	Causes severe skin burns and eye damage - Cat. 1 (H314)

[a] Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

[b] Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

[*] Existing Hazard Classification. No change recommended to this classification

Advice for consumers

Products containing the chemical should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from dermal, ocular and inhalation exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- air monitoring to ensure control measures in place are working effectively and continue to do so;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to help meet obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((M)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (M)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals—Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

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